K122366
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510(k) SUMMARY

As required by section 807.92

OCT 4 2012

Submitter	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 799 40 25 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.ch Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Type of 510k	SPECIAL
Preparation date	Revised September 9th 2012
Trade Name	TRYPTIK® Anterior Intersomatic Cervical Cage
Classification Name	Intervertebral body fusion device- Cervical
Class	II
Product Code	ODP
CFR section	888.3080
Device panel	Orthopedic
Legally marketed predicate devices	TRYPTIK® Anterior Intersomatic Cervical Cage manufactured by SPINEART (K091873); CRYSTAL manufactured by SPINAL ELEMENTS, INC (K073351); ALEUTIAN manufactured by K2M (K101302)
Description	The components added within this submission include lordotic and convex TRYPTIK® cc anterior intersomatic cervical cages. TRYPTIK® devices are made of PEEK OPTIMA LT1 conforming ASTM F2026. Markers made of titanium conforming ASTM F136 are used to visualize the position of the implant in the disc space. TRYPTIK® devices are designed for an anterior approach.
Intended Use	TRYPTIK® cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK® cages are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. TRYPTIK® cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment.
Performance data	TRYPTIK® cervical interbody fusion devices conform to Class II Special Controls Guidance Document: Intervertebral Body Fusion Device- Document issued on: June 12, 2007. Mechanical testing including Static and dynamic compression, static and dynamic shear, static and dynamic torsion tests have been performed according to ASTM F2077 and subsidence testing has been performed according to ASTM F2267. Results demonstrate that additional components perform as safely and effectively as their predicate devices. No clinical data has been presented.
Substantial equivalence	TRYPTIK® cervical interbody fusion devices are substantially equivalent to their predicate devices in terms of intended use, material, design, mechanical properties and function. Non clinical performance testing according to special control demonstrate that additional components are as safe, as effective, and performs as safely and effectively as their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SPINEART
% Mr. Frank Pennesi
Director of Industry and Quality
International Center Cointrin, 20 route de-Pré-bois
CP1813
1215 Geneva, Switzerland

OCT 4 2012

Re: K122366
Trade/Device Name: TRYPTIK® Anterior Intersomatic Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 10, 2012
Received: September 11, 2012

Dear Mr. Pennesi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122366

Device Name: TRYPTIK® Anterior Intersomatic Cervical Cage

Indications for Use:

TRYPTIK® cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. TRYPTIK® cages are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. TRYPTIK® cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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